DEC - 1 2006

**510(k) Number: K060792**

# PREMARKET NOTIFICATION 510(k) SUMMARY
# As required by §807.92

**Device Name – as required by 807.92(a)(2):**

| | |
|---|---|
| Trade Name: | **illumiMed™** |
| Common/Classification Name: | LED Phototherapy/Laser Instrument, Surgical, Powered and Infrared lamp |
| Classification Regulation(s): | 878.4810 and 890.5500 |
| Device Class: | **Class II** |
| Product Codes (Procode): | **GEX** and **ILY** |

Premarket Notification submitter:

| | |
|---|---|
| Company Name: | **PhotoActif, LLC** |
| Company Address: | **1959 South Power Road, Suite 103-313**<br>**Mesa, Arizona 85206** |
| Company Phone: | **(480) 827-1212** |
| Company FAX: | **(480) 827-1213** |
| Contact: | Jeremy Shellman, President and CEO |
| Preparation Date: | March 8, 2006 (amended October 19, 2006) |

**A. LEGALLY MARKETED PREDICATE DEVICE – as required by 807.92(a)(3).** For details, see **Exhibit 13**.

The identified legally marketed **GEX** predicate devices identified by the submitter are:

- **Omnilux Revive and Omnilux Plus Combination, K050216**, from Photo Therapeutics Limited, Cheshire, United Kingdom
- **Omnilux Blue, K030883**, from Photo Therapeutics Limited, Cheshire, United Kingdom
- **RevLight®, Skincare System, K042630**, from Skincare Technology Inc., Chicago, IL
- **AcneLift, K041103**, from Inner Act LLC, Reno, Nevada.

One legally marketed **ILY** predicate device is:

- **Omnilux Plus, K043317**, from Photo Therapeutics Limited, Cheshire, United Kingdom.

## B. DEVICE DESCRIPTION – as required by 807.92(a)(4)

The submitted device, **illumiMed**, is a treatment method using specific wavelengths of polychromatic energy produced by super-luminous LEDs (light emitting diodes) to treat a variety of skin and body conditions. It is an affordable, pain-free means to address a variety of dermatological concerns. The IR spectrum is intended to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promotion the relaxation of muscle tissue; and to temporarily increase local blood circulation. The blue spectrum is intended to reduce mild to moderate acne vulgaris. Use of the combination of blue, red and near infrared regions of the spectrum is intended to emit energy to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.

The control panel displays to the operator what treatment is being performed and provides the user with a choice of using the LED panels on the arm, LED attachments or both for any chosen treatment protocol.

The software component of the device controls an appropriate number of treatment protocols and each protocol can be enabled by a single action push-pad or button on the control panel. The software can be upgraded by the manufacturer.

## C. DEVICE CLAIMS - as required by 807.92(a)(4)

The illumiMed device is intended to emit energy to treat dermatological conditions including mild to moderate acne vulgaris. The illumiMed is intended to deliver heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.

## D. PRODUCT AND TECHNICAL SPECIFICATIONS - as required by 807.92(a)(4)

The illumiMed device is powered by grounded 120 volt electrical power with an operator controlled on/off switch. The device is housed in a unit that is mounted on four wheels allowing it to be moved to any location desired by the operator.

The control panel has push-pads or buttons that control its operation and software functionality. The software functionally can be upgraded by the manufacturer. The device has a panel arm extension that can hold between one (1) and five (5) LED panels and can be cantilevered in any direction for LED treatment of a patient in a prone, seated or standing position. The LED panels can be combinations of LEDs at ∀660 nm ("red"), ∀ 940-950 nm (near infrared), and ∀430 nm ("blue"). The panels can be configured as an individual panel or in combinations up to five panels of LEDs. Accessory LED pads and wands are available for additional treatment modalities with 660 nm, 940 nm and 430 nm LED diodes.

## E. INTENDED USE - as required by 807.92(a)(5)

The illumiMed device is intended to deliver heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. The blue spectrum is intended to reduce mild to moderate acne vulgaris. Use of the combination of blue, red and near infrared regions of the spectrum is intended to emit energy to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.

## F. INDICATIONS FOR USE – See **Exhibit 3.**

Use of 430 nm "blue" LEDs is intended to emit energy to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.

Use of the 660 nm "red" LEDs and of the 940 nm "near infrared" LEDs are indicated for delivery of heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.

Use of the accessory 38 blue LED Wand is intended to emit energy to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.

Use of the accessory 38 red/near infrared LED Wand is indicated for delivery of heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.

Use of the accessory 240 red/near infrared LED Pad is indicated for delivery of heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.

Use of the combination of 430 nm "blue" LEDs, 660 nm "red" LEDs and of the 940 nm "near infrared" LEDs is intended to emit energy to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.

## G. LEVEL OF CONCERN – as requested by recent FDA guidance

The FDA guidance document "***Guidance For The Content of Premarket Submissions For Software Contained In Medical Devices***," May 11, 2005, provides tables that the submitter used to identify the Level of Concern for the submitted device. See **Exhibit 4 – Level of Concern**.

The submitter, following approved procedures, assessed the device's software component for Level of Concern and completed the submitter's form **F 0014F, Level of Concern Assessment and Certification**.
Since the submitted device's software is neither a Major Level of Concern or a Moderate Level of Concern, **PhotoActif's** completed form **F 0014F** documents and the submitter claims the determination that the **illumiMed** device's software component can only be a **MINOR Level of Concern**.

## H. TECHNOLOGICAL CHARACTERISTICS SUMMARY – as required by 807.92(a)(6)

The technological characteristics available in **illumiMed** device include:

The submitted device provides a treatment method, using specific wavelengths of polychromatic energy produced by super-luminous LEDs (light emitting diodes), to treat a variety of skin and body conditions.

The device operates on grounded 110 volt power and is intended to be moved on its wheels to any appropriate location for use. The device has storage space for optional attachments and topicals.

A control panel provides for manual and software controlled treatment protocols, specifically with the:

1. Use of the four hundred ninety two (492) LED's panel-mounted on the panel arm with:

   Four hundred ninety two (492) 430 nm "blue" LEDs is intended to emit energy to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.

2. Use of the five hundred seventy six (576) LED's panel-mounted on the panel arm with:

   Two hundred eighty eight (288) 660 nm "red" LEDs and two hundred eighty eight (288) 940 nm "near infrared" LEDs is indicated for delivery of heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.

3. The use of the accessory thirty eight (38) LED Wand with:

   Twenty (20) 660 nm "red" LEDs and Eighteen (18) 940 nm "near infrared" LEDs is indicated for delivery of heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.

4. The use of the accessory thirty eight (38) LED Wand with:

   Thirty eight (38) 430 nm "blue" LEDs is intended to emit energy to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.

5. The use of the accessory two hundred forty (240) LED Pad with:

   One hundred twenty (120) 660 nm "red" LEDs and one hundred twenty (120) 940 nm "near infrared" LEDs is indicated for delivery of heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.

6. Use of the combination of 430 nm "blue" LEDs, 660 nm "red" LEDs and of the 940 nm "near infrared" LEDs:

   Is intended to emit energy to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris

   Currently, the device has software protocols that are activated by push-button controls on the Control Panel for:

   - Acne

   The device's Control Panel also provides for manual operation and has three (3) buttons, "A," "B," and "C," for future treatments that would be provided by the submitter as software updates to the current software version.

## TABLE OF SIMILARITIES AND DIFFERENCES BETWEEN illumiMed and the PREDICATE DEVICE(S)

| | GEX/ILY | GEX | | | GEX | ILY |
|---|---|---|---|---|---|---|
| **Characteristic** | **illumiMed** | **Omnilux Revive & Omnilux Plus Combo K050216** | **RevLight K042630** | **AcneLift K041103** | **Omnilux Blue K030883** | **Omnilux Plus K043317** |
| Electrical powered grounded 110 - 120 volts | Yes | Yes | Yes | Yes | Yes | Yes |
| LED diodes/infrared light | 430, 660, 940 nm | Revive: 633 nm Plus: 830 nm | "420 – 940 nm" | 405 nm | 417 nm | 830 nm |
| Interchangeable panels/modules | Yes | Yes | No | No | No | No |
| Wand Attachment | Yes | No | Yes | No | No | No |
| Pad Attachment | Yes | No | No | No | No | No |
| Energy Output in Joules | 430nm = 46 660nm & 940nm = 61 | *Revive = 126 *Plus = 66 | *48 | #50 | *48 | *66 |
| Energy Output in mw | 430nm = 3.5 660nm & 940nm = 31 | *Revive = 105 *Plus = 55 | *4200 | #45 | *40 | *55 |
| Software component | Yes | Yes | No | No | Yes | Yes |
| Software upgradeable | Yes | Unknown | n/a | No | Unknown | Unknown |
| Action to provide temporary relief of minor muscle aches and pain | Yes | Yes | Yes | No | No | Yes |
| Action to improve circulation | Yes | Yes | Yes | No | No | Yes |
| Action to provide temporary relief from arthritis and muscle spasm | Yes | Yes | No | No | No | Yes |
| Action to provide temporary relaxation of muscle tissue | Yes | Yes | Yes | No | No | Yes |
| Action to provide for photo-aged skin rejuvenation | Yes | Yes | No | No | No | Yes |
| Action to treat dermatological conditions and specifically for moderate inflammatory acne vulgaris | Yes | No | Yes | Yes | Yes | No |
| User Manual available | Yes | Yes | Yes | Yes | Yes | Yes |

* = information taken from company website # = information taken from company 510(k) submission

## I. SUBSTANTIAL EQUIVALENCE SUMMARY

The submitted device, **illumiMed**, has the same indications for use as the predicate devices.

**illumiMed** has the same or very similar technological characteristics as the identified predicate devices. However, while the submitter believes the characteristics are sufficiently precise to assure equivalence, the submitter has carried out validation and performance testing to further document substantial equivalence. The results of this testing substantiates that **illumiMed** performs as well as the predicate devices.

## J. CONCLUSIONS

The performance testing and validation studies document that **illumiMed** is substantially equivalent to the **GEX** predicates Omnilux Revive and Omnilux Plus Combination [K050216], Omnilux Blue [K030883], RevLight, Skincare System [K042630], and AcneLift [K041103]; and the **ILY** predicate Omnilux Revive [K030426].

The submitter's claim the submitted device is safe and effective for its intended use as both a prescription and non-prescription device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

PhotoActif, LLC
% Mr. Jeremy Shellman
President and CEO
1959 South Power Road,
Suite 103-313
Mesa, Arizona 85206

DEC - 1 2006

Re: K060792
Trade/Device Name: illumiMed™
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY, GEX
Dated: October 18, 2006
Received: October 20, 2006

Dear Mr. Shellman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K060792

Device Name: **illumiMed™**

## Indications For Use:

Use of 430 ±10 nm "blue" LEDs is intended to emit energy to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.

Use of the 660 ±10 nm "red" LEDs and of the 940 ±10 nm "near infrared" LEDs are indicated for delivery of heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase blood circulation.

Use of the accessory "38 blue LED Wand", 430 ±10 nm "blue", is intended to emit energy to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.

Use of the accessory "38 red/near infrared LED Wand", 660 ± 10nm "red" LEDs and of the 940 ±10 nm "near infrared" LEDs, is indicated for delivery of heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase blood circulation.

Use of the accessory "240 red/near infrared LED Pad", 660 ± 10nm "red" LEDs and of the 940 ±10 nm "near infrared" LEDs, is indicated for delivery of heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase blood circulation.

**510 (k) Number: K060792**

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____X____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K060792